



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/511,064  | 04/20/2005  | Scott Alan Jelinksy  | AM100877            | 8561             |
| 25291   | 7590        | 02/24/2006           | EXAMINER            |                  |
| WYETH<br>PATENT LAW GROUP<br>5 GIRALDA FARMS<br>MADISON, NJ 07940 |             |                      | LUNDGREN, JEFFREY S |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1639                |                  |

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                 |                  |
|------------------------------|---------------------------------|------------------|
| <b>Office Action Summary</b> | Application No.                 | Applicant(s)     |
|                              | 10/511,064                      | JELINKSY ET AL.  |
|                              | Examiner<br>Jeffrey S. Lundgren | Art Unit<br>1639 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 January 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-59 is/are pending in the application.  
 4a) Of the above claim(s) 5,6 and 8-59 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-4 and 7 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Applicants' election with traverse of Group I (claims 1-9) in the reply filed on January 11, 2006, is acknowledged. The traversal is on the grounds that it is not a serious burden for the Office to search claims directed to more than a single invention. This is not found persuasive because the search of more than one invention involves a divergent search wherein a substantial portion of the claimed subject matter found in one group is not found through the search of another group. For example, the pharmaceutical agents of Group XII, such as organic compounds, are likely to be outside the scope of the nucleotides/genes claimed in Group I.

Regarding Applicants election of species, it is noted that the vast array of genes in Group I do not constitute a common generic core structure, and accordingly represent and additional burden to search, especially considering that there currently is no allowable generic claim. Applicants' election of the species: 1) estrogen; 2) the single combination of all of ABCC3, NTTT73 and CYPB1; 3) BHMT and SAHH; and 4) the first group and second group.

Accordingly, claims 10-59 are withdrawn as being directed to a non-elected group, and claims 5, 6, 8 and 9 are currently withdrawn as being directed to non-elected species. Claims 1-4 and 7 are being examined on the merits.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 and 7 of the claimed invention are directed to non-statutory subject matter. Specifically, genes in their broadest form are non-statutory subject matter; Applicants' may overcome this rejection by amending the claims to recite, for example, "An isolated plurality of genes".

***Claim Rejections - 35 USC § 112, first paragraph (Written Description)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 7 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are directed to a plurality of any and all genes that are differentially expressed in kidney cells when exposed to estrogen and/or any other hormone. However, Applicants' disclosure only has limited support for the range of genes that appear to be differentially expressed, and only in response to a limited number of number or agents.

For example, Chern *et al.*, *Nephron* 85:258-266 (2000), explains the difficulty in proving a full set of differentially expressed kidney genes:

“Differential hybridization of ordinary cDNA libraries using total cDNA probes can only identify the abundant or moderately abundant genes differentially expressed. The method is not sensitive enough to isolate those genes expressed rarely and differentially [21]. We have screened by differential hybridization about 100,000 clones of an ordinary rat kidney cDNA library constructed in this laboratory and could not isolate any other genes differentially expressed between SHR and WKY (unpublished data).”

Chern, page 259.

In reviewing Applicants' disclosure, there appears to be no reasonable evidence to the contrary of Chern, that would lead one of ordinary skill in the art to believe that Applicants' had possession of the full scope of the invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Chern *et al.*, *Nephron* 85:258-266 (2000).

Claims 1-4 and 7, are directed to a plurality of genes differentially expressed in the kidney in response to estrogen. The claims are not limited to isolated genes, and therefore read on whole tissue.

These claims are anticipated two ways by Chern: 1) the actual whole kidney tissue of Chern (page 259, Materials and Methods); and 2) the array of kidney genes, such as the 100,000 cDNA array and those listed in Table 1 (pages 260, 261 and 265). Regarding the fact that the genes are expressed higher or lower in response to estrogen is an inherent property, and need not be taught by Chern, only the genes themselves or the kidney having those genes.

Accordingly, claims 1-4 and 7 are anticipated.

### ***Conclusions***

No claims are allowable.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached on 8:30 AM to 5:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSL

*Jon Epperson*  
*Jn*